

TArgeting Type 1 Diabetes Using POLyamines (TADPOL): A Randomized, Double-Masked, Placebo-Controlled Phase 2 Study to Evaluate the Efficacy and Safety of Difluoromethylornithine (DFMO) to Preserve Insulin Production in Type 1 Diabetes

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Not specified

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 4 to 40 years old - diagnosis of Type 1 Diabetes (T1D) and started insulin no more than 100 days before starting this clinical trial - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- any severe, active disease that interferes with food intake or requires the use of chronic medication, with the exception of well-controlled hypothyroidism and mild asthma not requiring oral steroids - unable to swallow pills - current use of anti-psychotic medication - allergy to milk or soy - women & men of child bearing age must agree to use approved birth control - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:

Diabetes & Endocrine

Keywords:

T1D, Type 1 Diabetes

More Information

Description: This study is looking at the safety and effects of Difluoromethylornithine (DFMO) and its effect on insulin production in people who have been newly diagnosed with type 1 diabetes. DFMO is a drug that is FDA-approved for other uses, but is being looked at in this study for preserving beta cell function. Participants will be randomized (like flipping a coin) to take either the placebo medicine or Difluoromethylornithine (DFMO) for 6 months followed by 6 months of no medication. Of all people participating in the study, 2 out of 3 people will receive DFMO and 1 out of 3 people will receive placebo treatment. Participation in this study will be approximately 12 months.

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Phase: PHASE2

IRB Number: STUDY00024995

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